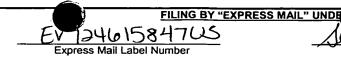
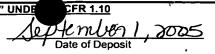
JC01 Rec'd PCT/PTO Q1 SEP 32005

AD





#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF BURKHART ET AL.

INTERNATIONAL APPLICATION NO: PCT/EP2003/010700

FILED: 25 SEPTEMBER 2003

U.S. APPLICATION NO: 10/529,166 35 USC §371 DATE: 8 AUGUST 2005

FOR: TCELL MEDIATOR/MODULATOR ASSAY BASED UPON TCELL

RESTRICTED TRANSGENIC MOUSE

MS: PCT Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

# COMMUNICATION IN RESPONSE TO THE NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. § 371

Sir:

On August 4, 2005, the USPTO issued the Notification of Missing Requirements Under 35 U.S.C. § 371, a copy of which is enclosed.

This undersigned submitted the executed Declaration to the USPTO on August 8, 2005 in a Second or Subsequent Submission of Items Concerning a Filing Under 35 U.S.C. § 371. Enclosed please find a copy this Second or Subsequent Submission, a copy of the executed Declaration, and a copy of the date stamped postcard from the USPTO acknowledging receipt by the PCT/PTO on August 8, 2005.

Because Applicants submitted the executed Declaration on August 8, 2005 with authorization to charge the \$130 late fee and any additional fees to our Deposit Account, no fee is required.

**Novartis** 

Corporate Intellectual Property One Health Plaza, Building 104 East Hanover, NJ 07936-1080

(862) 778-2614 Date: **GL** 

te: 9/1/05

Respectfully submitted,

Gregory C. Houghton Attorney for Applicants Reg. No. 47,666



1095

**NOVARTIS** 

#### PATENT AND TRADEMARK OFFICE UNITED STATE:

INITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS O. Dox 1450 Alexandra, Viginia 22313-1450 www.upptu.gov

FIRST NAMED APPLICANT U.S. APPLICATION NUMBER NO.

ATTY, DOCKET NO. PD/4-32516A

10/529,166

**EAST HANOVER, NJ 07936-1080** 

Christoph Burkhart

INTERNATIONAL APPLICATION NO.

PCT/EP03/10700

I.A. FILING DATE

09/25/2003

PRIORITY DATE 09/26/2002

CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3

**CONFIRMATION NO. 4328 371 FORMALITIES LETTER** 

\*OC00000016687865\*

Date Mailed: 08/04/2005

## NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 03/24/2005
- Copy of the International Search Report filed on 03/24/2005
- Preliminary Amendments filed on 03/24/2005
- Information Disclosure Statements filed on 03/24/2005
- U.S. Basic National Fees filed on 03/24/2005
- Priority Documents filed on 03/24/2005

Linda C. Rothwell

The following items MUST be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- \$130 Surcharge for providing the oath or declaration later than 30 months from the priority date (37 CFR) 1.492(e)) is required.

#### SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

\$130 Late oath or declaration Surcharge.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

DOCKETED FOR: Oct 4

of 37 CFR 1.136(a).

The time period set above mage extended by filing a petition and fee for ex



Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

A copy of this notice MUST be returned with the response.

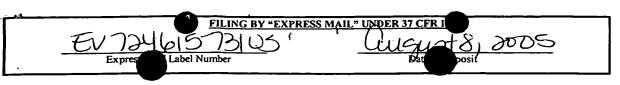
PATRICIA A BOOKER

Telephone: (703) 308-9140 EXT 204

### PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/529,166	PCT/EP03/10700	PD/4-32516A

FORM PCT/DO/EO/905 (371 Formalities Notice)



Form ! (REV			Department of Commerce Patent and Trademark Office	ATTORNEY'S DOCKET NUMBER PD/4-32516A					
		TRANSMITTAL LETTER TO 1	HE UNITED STATES	U.S. APPLICATION NO. (If known, see 37 CFR 1.5)					
		DESIGNATED/ELECTED O	FFICE (DO/EO/US)	10/529,166					
		CONCERNING A FILING UN							
INT	ER	NATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED					
PC1	T/E	P2003/010700	25 September 2003 (25.09.03)	26 September 2002 (26.09.02)					
TITI	LE	OF INVENTION							
		MEDIATOR/MODULATOR ASSAY B	ASED UPON TCELL RESTRICTED	TRANSGENIC MOUSE					
APF		CANT(S) FOR DO/EO/US							
BURKHART ET AL.									
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:									
1. This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.									
	씽	This is a SECOND or SUBSEQUENT sub	omission of items concerning a filing un	der 35 U.S.C. 371.					
	$\Box$	This express request to begin national ex							
4.			blicable time limit set in 35 U.S.C. 371(b inary Examination was made by the 19	i) and PCT Articles 22 and 39(1). The month from the sadiest claimed priority					
5.		date. A copy of the International Application as	filed (35 U.S.C. 371(c)(2))						
		b.  has been transmitted by the Interr	only if not transmitted by the Internation national Bureau. (See Form PCT/IB/30	8)					
_	_	c. is not required, as the application	was filed in the United States Receiving	g Office (RO/US).					
6. 7.	님	A translation of the International Application  Amendments to the claims of the International Amendments to the claims of the International Amendments to the claims of the International Amendments to the International Amendment International Amendment International Amendment International Intern	on into English (35 U.S.C. 371(c)(2)). Ional Application under PCT Article 19 (	35 U.S.C.371(c)(3)).					
7.	ب	a. are transmitted herewith (required	only if not transmitted by the Internation						
		b. have been transmitted by the Inte		to has NOT surried					
		c. have not been made; however, the	e time ilmit for making such amendmen be made.	ns has NOT expired.					
8. j		A translation of the amendments to the cla	aims under PCT Article 19 (35 U.S.C. 3						
	=	An executed Declaration and Power of Att A translation of the annexes to the Interna	orney (original or copy) (35 U.S.C. 371	(C)(4)).					
10.	Ц	371(c)(5)).	donal Freilminary Examination Report	under FC1 Article 30 (35 U.S.C.					
•									
Item	s 1	: 1. to 16. below concern document(s) or i	nformation included.						
11.	$\boxtimes$	A Supplemental Information Disclosure Sta	atement under 37 CFR 1.97 and 1.98.						
12. [		An assignment document for recording. A	separate cover sheet in compliance w	ith 37 CFR 3.28 and 3.31 is included.					
13. [		A FIRST preliminary amendment.		•					
. [		A SECOND or SUBSEQUENT preliminary	amendment.						
14. [		An Application Data Sheet under 37 CFR 1	1.76.						
15. [		A substitute specification.							
16. [		A change of power of attorney and/or address	ess letter.						
17. [		A computer-readable form of the sequence	listing in accordance with PCT Rule 1	3ter.2 and 37 CFR 1.821-1.825.					
18. [		A second copy of the published Internation	al Application under 35 U.S.C. 154(d)(	4)					
19. [	]	A second copy of the English language tran	nslation of the International application	under 35 U.S.C. 154(d)(4).					
20. [	)	Other items or information:							

U.S. APPLICATION N 10/529,166	IO. (if knowr	n, see 37 CFR 1.5)		INTERNATIONAL APPLICATIO PCT/EP2003/01070				PD/4-325		UMBER	
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All o	All other situations								-		
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If Se	earch fee			nas been paid on the				•			
lf in	application to the USPTO as an International Searching Authority \$  If International Search Report was prepared and provided to the Office \$  All other situations										
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c.  The Con	nmissior Account	ner is hereby : No. 19-013	authorized in the nam	to charge any additi ne of Novartis.	ional fee	s whic	ch may	be required,	or credi	t any ove	erpayment to
NOTE: Where a	n appro	priate time l	limit under	37 CFR 1.494 or 1. application to pen	495 has	not b	oeen me	et, a petitio	n to revi	ve (37 C	FR 1.137(a)
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Novartis Corporate	Intellect	tual Property	,		Attorfro	ey for	Applica	ants			
One Healt	h Plaza,	Building 10	4		(862) 7						
East Hand	ver, NJ	07936-1080			•						

# DECLARATION AND POWER OF ATTORNEY FOR UNITED STATES PATENT APPLICATION

×	Original		Supplemental		Substitute
	a below named inventor, I here	•			
Муг	residence, post office address	and	citizenship are as stated below next to	my r	name, and
and	lieve I am the original, first an joint inventor (if more than one th a United States patent is soo	e nar	le inventor (if only one name is listed ne is listed below) of the subject matte on the invention entitled	belov er wh	w) or an original, first ich is claimed and for
TCE MOL		RAS	SAY BASED UPON TCELL RESTRIC	CTE	TRANSGENIC
the s	specification of which:				
	is attached hereto.				
	was filed on (day	/mon	as Application No	<del></del>	
	and, if this box (□) contains	an	×		
	was amended on			,	
	•	(day	//month/year)		
X	was filed as Patent Coopera		Treaty international Application No. on 25/09/03 (day/month/year)		
	and, if this box (□) contains	an ۶	•		
	☐ entered the national	stad	e in the United States and was accord	ded A	Application No.
•		- 0			Application 110.
	and, if this box (□) contains	an y	•		·
	☐ was amended, subse	eque	nt to entry into the national stage, on		
	•				(day/month/year)

I hereby state that I have reviewed and understand the contents of the above-identified specification. including the claims, as amended by any amendment(s) specifically referred to above and, if this application was filed as a Patent Cooperation Treaty international application, by any amendments made during the international stage (including any made under Patent Cooperation Treaty Rule 91, Article 19 and Article 34).

I acknowledge my duty to disclose information which is material to patentability as defined in 37 C.F.R. 1.56, including, for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or Patent Cooperation Treaty international filing date of the continuation-in-part application.

I hereby claim the benefit under 35 U.S.C. 119(a)-(d) or (f) or 365(b) of any foreign application(s) for patent, inventor's certificate or plant breeder's right certificate listed below and under 35 U.S.C. 365(a) of any Patent Cooperation Treaty international application(s) designating at least one country other than the United States listed below and have also listed below any foreign application(s) for patent, inventor's certificate or plant breeder's right certificate and Patent Cooperation Treaty international application(s) designating at least one country other than the United States for the same subject matter and having a filing date before that of the application the priority of which is claimed for that subject matter:

COUNTRY/REGION (OR P.C.T.)	APPLICATION No.	FILING DATE (day/month/year)	PRIORITY CLAIMED		
			☐ Yes	□ No	
	·		☐ Yes	□ No	
			□ Yes	□ No	
•			☐ Yes	□ No	
			☐ Yes	□ No	

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below:

APPLICATION NO.	FILING DATE (day/month/year)	
60/413706	26/09/02	
60/413702	26/09/02	
60/413703	26/09/02	

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s) listed below and under 35 U.S.C. 365(c) of any Patent Cooperation Treaty international application(s) designating the United States listed below:

United States	United States	Status (Pending,	International		
Application No.	Filing Date	Abandoned or U.S.	Application No.	and Filing Date	
	(day/month/year)	Patent No.)		(day/month/year)	

I hereby appoint all the registered practitioners associated with the mer No. 001095, respectively and individually, as my attorneys and agents, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

If this box ( $\square$ ) contains an x  $\boxtimes$ , I hereby authorize the registered practitioners associated with Customer No. 001095 and any others acting on my behalf to take any action relating to this application based on communications from Corporate Intellectual Property of Novartis International AG, Basle, Switzerland, or an affiliate thereof or a successor thereto, without direct communication from me.

Please send all correspondence relating to this application to the address associated with Customer No. 001095.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

			<del></del>
Full name of sole or first joint inventor	Christoph BURKHART		
Inventor's signature	Chrism Bralt	Date	19/64/2005 (day/month/year)
Residence	1130 Vienna, Austria,		
Citizenship	Austria		
Post Office Address	Stuweckengasse 9, 1130 Vienna, Austria		
Full name of second joint inventor, if any	Ekke LIEHL		
Inventor's signature		Date	·
			(day/month/year)
Residence	2371 Hinterbrühl, Austria		
Citizenship	Germany		
Post Office Address	Badgasse 12/2, 2371 Hinterbrühl, Austria		

IMPORTANT: Before this declaration is signed, the patent application (the specification, the claims and this declaration) must be read and understood by each person signing it, and no changes may be made in the application after this declaration has been signed.

Full name of third			
joint inventor, if any	Peter MAYER		
Inventor's signature		Date	
mventor 3 signature			(day/month/year)
Residence	1130 Vienna, Austria		
Citizenship	Austria		• •
Post Office Address	Trauttmannsdorffgasse 32/4, 1130 Vienna, Austria		
Full name of fourth joint inventor, if any			
Inventor's signature		Date _	(1
•			(day/month/year)
Residence			
Citizenship			
Post Office Address			
•			
Full name of fifth			
joint inventor, if any			
Inventor's signature		Date	.*
			(day/month/year)
Residence			
Citizenship	: ·		
Post Office Address	en e		



×	Original		Supplemental		Substitute
As a	a below named inventor, I heret	by de	eclare that:		
Муι	residence, post office address a	and d	citizenship are as stated below next to	my r	name, and
and		nam	e inventor (if only one name is listed ne is listed below) of the subject matte on the invention entitled		
TCE MOI		R AS	SAY BASED UPON TCELL RESTRIC	CTEC	TRANSGENIC
the s	specification of which:				
	is attached hereto.				
	was filed on (day/	mont	as Application No.		
	and, if this box (□) contains	an 3	¢		
	□ was amended on			*	•
	<u>-</u>	(day	/month/year)		
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	and, if this box (□) contains	an ×	<u> </u>		
			nt to entry into the national stage, on		
		- <b>-</b>		_	(day/month/year)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) specifically referred to above and, if this application was filed as a Patent Cooperation Treaty international application, by any amendments made during the international stage (including any made under Patent Cooperation Treaty Rule 91, Article 19 and Article 34).

I acknowledge my duty to disclose information which is material to patentability as defined in 37 C.F.R. 1.56, including, for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or Patent Cooperation Treaty international filing date of the continuation-in-part application.

60/413703

I hereby claim the benefit under 35 U.S.C. 119(a)-(d) or (f) or 365(b) of any foreign application(s) for patent, inventor's certificate or plant breeder's right certificate listed below and under 35 U.S.C. 365(a) of any Patent Cooperation Treaty international application(s) designating at least one country other than the United States listed below and have also listed below any foreign application(s) for patent, inventor's certificate or plant breeder's right certificate and Patent Cooperation Treaty international application(s) designating at least one country other than the United States for the same subject matter and having a filing date before that of the application the priority of which is claimed for that subject matter:

·			T						
COUNTRY/REGION (OR P.C.T.)	APPLICATION No.	FILING DATE (day/month/year)	PRIO	RITY CLAIMED					
			☐ Ye	s 🗆 No					
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			☐ Ye	s 🗆 No					
<i>.</i> •			☐ Ye	s 🗆 No					
			☐ Ye	s 🗆 No					
I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below:									
APPLICATION NO.		FILING DATE (day/month/year)							
60/413706		26/09/02	•						
60/413702	•	26/09/02		•					

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s) listed below and under 35 U.S.C. 365(c) of any Patent Cooperation Treaty international application(s) designating the United States listed below:

26/09/02

				·· · · · · · · · · · · · · · · · · · ·	
United States	United States	Status (Pending,	International		
Application No.	Filing Date	Abandoned or U.S.	Application No.	and Filing Date	
друшацан на	(day/month/year)	Patent No.)		(day/month/year)	

US

I hereby appoint all the registered practitioners associated with the mer No. 001095, respectively and individually, as my attorneys and agents, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

If this box ( $\square$ ) contains an x  $\boxtimes$ , I hereby authorize the registered practitioners associated with Customer No. 001095 and any others acting on my behalf to take any action relating to this application based on communications from Corporate Intellectual Property of Novartis International AG, Basle, Switzerland, or an affiliate thereof or a successor thereto, without direct communication from me.

Please send all correspondence relating to this application to the address associated with Customer No. 001095.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Full name of sole or first joint inventor	Christoph BURKHART		
Inventor's signature		Date .	(day/month/year)
Residence	1130 Vienna, Austria,		·
Citizenship	Austria		
Post Office Address	Stuweckengasse 9, 1130 Vienna, Austria		
Full name of second joint inventor, if any	Ekke LIEHL		
Inventor's signature	S. Lule	Date -	(day/month/year)
Residence	2371 Hinterbrühl, Austria		
Citizenship	Germany		
Post Office Address	Badgasse 12/2, 2371 Hinterbrühl, Austria		

IMPORTANT: Before this declaration is signed, the patent application (the specification, the claims and this declaration) must be read and understood by each person signing it, and no changes may be made in the application after this declaration has been signed.

Full name of third joint inventor, if any	Peter MAYER		
Inventor's signature	P. chouse	Date _	11. 4. LOOS (day/month/year)
Residence	1130 Vienna, Austria		
Citizenship	Austria		
Post Office Address	Trauttmannsdorffgasse 32/4, 1130 Vienna, Austria		
Full name of fourth joint inventor, if any			
Inventor's signature		Date	(day/month/year)
Residence			
Citizenship			
Post Office Address			
Full name of fifth joint inventor, if any	.*		
Inventor's signature		_ Date	
			(day/month/year)
Residence			
Citizenship	·		
Post Office Address			

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF

BURKHART ET AL.

INTERNATIONAL APPLICATION NO: PCT/EP2003/010700

FILED: 25 SEPTEMBER 2003

U.S. APPLICATION NO: 10/529,166 35 USC §371 DATE: Not Yet Known

FOR: TCELL MEDIATOR/MODULATOR ASSAY BASED UPON TCELL

RESTRICTED TRANSGENIC MOUSE

MS: Amendment Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

#### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

This paper is supplemental to the Information Disclosure Statement filed March 24, 2005. Since it is being filed within three months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 of the international application, no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-0134.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

Copies of these references are enclosed herewith.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted.

Gregory / Houghton

Attorney for Applicants

Reg. No. 47,666

Novartis Corporate Intellectual Property One Health Plaza, Building 104 East Hanover, NJ 07936-1080 (862) 778-2614

FORM PTO-1449
(REV. 7-85)
U.S. DEF MENT OF COMMERCE PATENT AND TRADEMARK OFFICE
INFORMATION DISCLOSURE CITATION
(Use several sheets if newly)

ATTY. DEET NO. PD/4-32516A
APPLICATION NO. 10/5 6
APPLICATION THE BURKHART ET AL. FILING DATE
Herewith

Group

			U.S.	. PAT	ENT DOCUMENTS				
EXAMINER INITIAL	DOCUMENT NUMBER DATE			NAME	CLASS	SUBCLASS	FILI	NG DATE	
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	AP	97/08303	3/6/97	wc	)				
	AQ	99/16867	4/8/99	wc	·				
	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)								
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EXAMINE	R				DATE CONSIDERED				

\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

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#### **FOREIGN PATENT DOCUMENTS**

EXAMINER	,	DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRAN	SLATION
INITIAL		DOCOMENT NOMBER	DAIL	01102	02.00	0000000	YES	NO
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		Hari et al., "T Cell Involvement in Cutaneous Drug Eruptions", Clinical and Experimental Allergy,		
	CA	Vol. 31, pp. 1398-1408 (2001).		
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	CD	Jenkins et al., "In Vivo Activation of Antigen-Specific CD4 T Cells", Annu. Rev. Immunol. Vol. 19, pp. 23-45 (2001).		
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	CK.			
	CL			
	СМ			
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<sup>\*</sup>EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

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